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Thomas S. Birney, Esq.
Dorr, Carson, Sloan & Birney, P.C.
3010 E. 6th Avenue
Denver, CO 80206

EXAMINER	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/818,228
Filing Date: March 27, 2001
Appellant(s): CHRISTOPHER, KENT L.

Thomas S. Birney
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 5/7/04.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is substantially correct. The changes are as follows: Please note that with respect to Issue 1, the Examiner hereby withdraws the rejection of claim 25; with respect to Issue 4, the Examiner hereby withdraws the rejection of claims 5 and 18; and with respect to Issue 7, the Examiner hereby withdraws the rejection of claim 24.

(7) Grouping of Claims

Appellant's brief includes a statement that claims 1, 2, 6, 8, 11-15, 20, 23, 25, and 28; 3 and 6; 4 and 17; 5 and 18; 7 and 19; 9, 10, 21, 22, 26, and 27; and 24 do not

stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

6,394,093	LETHI	5-2002
6,374,827	BOWDEN et al	4-2002
6,050,260	DANIELL et al	4-2000
6,055,984	BRAIN	5-2000
5,297,546	SPOFFORD et al	3-1994

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1, 2, 6, 8, 11-15, 20, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lethi (US 6394093).

3. **As to claim 1**, Lethi teaches a nasopharyngeal catheter for open delivery of a continuous air/oxygen into a patient's distal nasopharynx or oropharynx to supplement a patient's spontaneous respiration in treatment of respiratory failure, respiratory insufficiency, or sleep apnea syndrome, the nasopharyngeal catheter comprising a nasal catheter **1** having a proximal end and a distal end adapted to extend through a patient's nose and into the patient's distal nasopharynx or oropharynx without restricting the patient's spontaneous respiration; a delivery tube **9** adapted to extend below the patient's nostril connected to the proximal end of the nasal catheter; and a gas source. It should be noted that Lethi fails to specifically teach a flow rate of approximately 4 to 40 liters per minute. However, Applicant has not stated how the particular flow rate solves a stated problem or is advantages over the prior art of record or provides unexpected results. Furthermore, the particulars of the flow rate would depend on the intended use, intended patient (infant, child, adult), and intended therapy. For example, a flow rate suitable for an adult may not be suitable for a neonate or a premature baby as the flow rate that is suitable for an adult might blow/rupture/damage a neonate or premature baby's lungs. Therefore, it would be obvious to one of ordinary skill in the art to provide a flow rate within the range of 4 to 40 liters per minute based on the intended use, intended patient, and intended therapy.

4. **As to claim 2**, Lethi teaches a nasopharyngeal catheter wherein the nasal catheter comprises a flexible plastic tube that can be cut to a desired length.

5. **As to claim 6**, Lethi teaches essentially all of the limitations except for a connector for removably attaching the proximal end of the nasal catheter to the delivery

tube. However, it would be obvious to one of ordinary skill in the art to provide such a connector in Lethi so that if the pieces needed to be cleaned or replaced it would be easy to do so without having to discard the entire device.

6. **As to claim 8**, Lethi teaches essentially all of the limitations except for wherein the nasal catheter has an inside diameter of up to approximately 3 mm. Applicant has not stated how the particular dimension solves a stated problem or is advantages over the prior art of record or provides unexpected results. Furthermore, the particular of the dimension would depend on the intended patient (infant, child, adult). Additionally, Lethi states that a "variety of airway tube diameters and lengths would be available for the differences in the physical dimensions of various patients. Therefore, it would be obvious to one of ordinary skill in the art to provide a particular dimension based on the intended patient.

7. **As to claim 11**, Lethi teaches essentially all of the limitations except for wherein gas is supplied through the nasal catheter at a back pressure of up to approximately 25 psi. However, Applicant has not stated how the particular back pressure solves a stated problem or is advantages over the prior art of record or provides unexpected results. Furthermore, the particulars of the pressure would depend on the intended use, intended patient (infant, child, adult), and intended therapy. Therefore, it would be obvious to one of ordinary skill in the art to provide a back pressure of 25 psi based on the intended use, intended patient, and intended therapy.

8. **As to claims 12**, Lethi teaches a nasopharyngeal catheter wherein the gas supplied through the nasal catheter comprises oxygen.

9. **As to claims 13**, Lethi teaches a nasopharyngeal catheter wherein the gas supplied through the nasal catheter comprises air.

10. **As to claim 14**, Lethi teaches essentially all of the limitations except for wherein the gas supplied through the nasal catheter comprises helium. However, Applicant has not stated how the particular gas supplied solves a stated problem or is advantages over the prior art of record or provides unexpected results. Furthermore, the particulars of the gas supplied would depend on the intended use, intended patient (infant, child, adult), and intended therapy. Therefore, it would be obvious to one of ordinary skill in the art to provide a specific gas such as helium based on the intended use, intended patient, and intended therapy.

11. **As to claim 15**, Lethi teaches a nasopharyngeal catheter comprising a nasal catheter **1** having a proximal end and a distal end adapted to extend through a patient's nose and into the patient's distal nasopharynx or oropharynx without restricting the patient's spontaneous respiration; the catheter being made of flexible material that can be trimmed to a desired length; a delivery tube **9** adapted to extend below the patient's nostril having a connector for attachment to the proximal end of the nasal catheter; and a gas source. It should be noted that Lethi fails to specifically teach a removable connector. However, it would be obvious to one of ordinary skill in the art to provide such a connector in Lethi so that if the pieces needed to be cleaned or replaced it would be easy to do so without having to discard the entire device. It should be noted that Lethi fails to specifically teach a flow rate of approximately 4 to 40 liters per minute. However, Applicant has not stated how the particular flow rate solves a stated problem

or is advantages over the prior art of record or provides unexpected results. Furthermore, the particulars of the flow rate would depend on the intended use, intended patient (infant, child, adult), and intended therapy. Therefore, it would be obvious to one of ordinary skill in the art to provide a flow rate within the range of 4 to 40 liters per minute based on the intended use, intended patient, and intended therapy.

12. **As to claim 20**, Lethi teaches essentially all of the limitations except for wherein the nasal catheter has an inside diameter of up to approximately 3 mm. Applicant has not stated how the particular dimension solves a stated problem or is advantages over the prior art of record or provides unexpected results. Furthermore, the particular of the dimension would depend on the intended patient (infant, child, adult). Additionally, Lethi states that a "variety of airway tube diameters and lengths would be available for the differences in the physical dimensions of various patients. Therefore, it would be obvious to one of ordinary skill in the art to provide a particular dimension based on the intended patient.

13. **As to claim 23**, Lethi teaches a method for providing a supplemental continuous flow of air/oxygen to a spontaneously breathing patient, the method comprising advancing a nasopharyngeal catheter through a patient's nostril until the distal tip of the catheter is located in the patient's distal nasopharynx or oropharynx without obstructing the patient's spontaneous respiration. It should be noted that Lethi fails to specifically teach the step of supplying air/oxygen through the catheter at a flow rate of approximately 4 to 40 liters per minute. However, Applicant has not stated how the particular flow rate solves a stated problem or is advantages over the prior art of record

or provides unexpected results. Furthermore, the particulars of the flow rate would depend on the intended use, intended patient (infant, child, adult), and intended therapy. Therefore, it would be obvious to one of ordinary skill in the art to provide a flow rate within the range of 4 to 40 liters per minute based on the intended use, intended patient, and intended therapy.

14. **As to claim 28**, Lethi teaches essentially all of the limitations except for wherein the gas supplied through the nasal catheter comprises helium. However, Applicant has not stated how the particular gas supplied solves a stated problem or is advantages over the prior art of record or provides unexpected results. Furthermore, the particulars of the gas supplied would depend on the intended use, intended patient (infant, child, adult), and intended therapy. Therefore, it would be obvious to one of ordinary skill in the art to provide a specific gas such as helium based on the intended use, intended patient, and intended therapy.

15. Claims 3 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lethi in view of Bowden et al (US 6374827).

16. **As to claims 3 and 16**, Lethi teaches essentially all of the limitations except for wherein the nasal catheter further comprises a plurality of markings indicating a series of common lengths for the nasal catheter. However, Bowden does teach a plurality of markings for a variety of positions for different sized patients or children and for determining proper insertion. Therefore, it would be obvious to one of ordinary skill in the art to modify the catheter of Lethi to include a plurality of markings as taught by

Bowden for a variety of positions for different sized patients or children and for determining proper insertion.

17. Claims 4 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lethi in view of Brain (US 6055984).

18. **As to claims 4 and 17**, Lethi teaches essentially all of the limitations except for wherein the nasal catheter comprises a radio-opaque stripe. However, Brain does teach the use of a radio-opaque stripe to allow for easy identification of the location of a tube. Therefore, it would be obvious to one of ordinary skill to modify the catheter of Lethi to include a radio-opaque stripe as taught by Brain stripe to allow for easy identification of the location of the catheter.

19. Claims 7 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lethi in view of Spofford et al (US 5297546).

20. **As to claim 7**, Lethi teaches a nasal catheter having essentially all of the claimed limitations except for the catheter comprising a hydrophilic coating. Spofford et al teaches a catheter comprising a hydrophilic coating for limiting adhesion and subsequent build-up of mucous-type materials which would restrict the flow of oxygen through the catheter. Therefore, it would be obvious to one of ordinary skill in the art to modify Lethi's catheter to have a hydrophilic coating for limiting adhesion and subsequent build-up of mucous-type materials which would restrict the flow of oxygen through the catheter.

21. **As to claim 19**, Lethi teaches a nasal catheter having essentially all of the claimed limitations except for the catheter comprising a hydrophilic coating. Spofford et

al teaches a catheter comprising a hydrophilic coating for limiting adhesion and subsequent build-up of mucous-type materials which would restrict the flow of oxygen through the catheter. Therefore, it would be obvious to one of ordinary skill in the art to modify Lethi's catheter to have a hydrophilic coating for limiting adhesion and subsequent build-up of mucous-type materials which would restrict the flow of oxygen through the catheter.

22. Claims 9, 10, 21, 22, 26, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lethi in view of Daniell et al (US 6050260).

23. **As to claim 9**, Lethi teaches essentially all of the claimed limitations except for a humidifier controlling the humidity of the gas delivered through the nasal catheter. However, Daniell does teach a humidifier for humidifying the gases delivered to the patient in order to prevent dehydration of the airways and nasal passages of the patient. Therefore, it would have been to one of ordinary skill in the art to modify Lethi's device to include a humidifier for humidifying the gases delivered to the patient in order to prevent dehydration of the airways and nasal passages of the patient.

24. **As to claim 10**, the above combination teaches a nasopharyngeal catheter comprising a heater for controlling the temperature of the gas delivered through the catheter.

25. **As to claim 21**, Lethi teaches essentially all of the claimed limitations except for a humidifier controlling the humidity of the gas delivered through the nasal catheter. However, Daniell does teach a humidifier for humidifying the gases delivered to the patient in order to prevent dehydration of the airways and nasal passages of the patient.

Therefore, it would have been to one of ordinary skill in the art to modify Lethi's device to include a humidifier for humidifying the gases delivered to the patient in order to prevent dehydration of the airways and nasal passages of the patient.

26. **As to claim 22**, the above combination teaches a nasopharyngeal catheter comprising a heater for controlling the temperature of the gas delivered through the catheter.

27. **As to claim 26**, Lethi teaches essentially all of the limitations except for the method further comprising controlling the humidity of the air/oxygen supplied through the catheter. However, Daniell teaches the method of controlling the humidity of the gas delivered through the nasal catheter in order to prevent dehydration of the airways and nasal passages of the patient. Therefore, it would have been to one of ordinary skill in the art to include the method of Daniell for humidifying the gases delivered to the patient in order to prevent dehydration of the airways and nasal passages of the patient.

28. **As to claim 27**, the above combination teaches a method regulating the temperature of air/oxygen supplied through the catheter.

(11) Response to Argument

29. In response to Appellant's arguments with respect to Issue 1 and that "With unrestricted spontaneous breathing, the nasopharynx serves to heat, humidify and filter air. These natural functions are prevented with the Lethi invention," it should be noted that Appellant's device does not provide unrestricted spontaneous breathing in the nasopharynx region since insertion of any object in an orifice or opening would lead to obstruction or restriction in some manner. Therefore, the Examiner maintains that the

Lethi device does not restrict the nasopharynx or oropharynx in so much as does the Applicant's device. Furthermore, the cuff of Lethi does not have to be inflated and therefore would not restrict the nasopharynx or oropharynx. Furthermore, claim 1 specifically recites "...without restricting the patient's spontaneous respiration through the patient's nasopharynx **or** oropharynx..." and as such there is unrestricted spontaneous respiration through the mouth leading into the oropharynx region. Next, Appellant argues that the Lethi device is intended for short-term use in surgery or post-op recovery and not for "truly conscious patients". In response, the Examiner contends that Appellant has not limited use of the device in the claims to "truly conscious patients" or for long-term use. It should be noted that Lethi does teach the use of the device for supply continuous oxygen to conscious or unconscious patients (See Col. 3, lines 5-6 of Lethi). In response to Appellant's arguments that Lethi does not teach or suggest a gas source with a flow rate of 4-40 liters per minute, the Examiner maintains that Appellant has not stated how the particular flow rate solves a stated problem, is advantages over the prior art, or provides an unexpected result(s). Also, the particulars of the flow rate would depend on the intended use, intended patient (infant, child, adult), and intended therapy. Finally, the Examiner would like to elaborate on the gas source taught by Lethi. Lethi teaches one source of gas to be a hospital room oxygen supply system (See Col. 4, lines 53-59 of Lethi). A hospital room oxygen supply system is inherently capable of delivering oxygen with a flow rate of 4-40 L/min. In response to Appellant's arguments with respect to claims 2 and 15, Lethi does teach a flexible tube (See Figs. 1 and 2 which show flexibility of the tube) and hence the flexibility of the tube allows for

the tube to be capable of being trimmed. In response to Appellant's arguments with respect to the use of helium as a source of gas, the Examiner maintains that the particular type of gas used would again depend on the intended use, intended patient (infant, child, adult) and intended therapy and such would be obvious to one of ordinary skill in the art. Appellant further supports the Examiner's rejection with respect to the use of helium in the specification. In the specification, the Appellant outlines the use of various gases for various functions thus commensurate with the Examiner's rejection that the use of a particular gas is dependent on the intended use/therapy and would be obvious to one of ordinary skill in the art to use a particular gas for a particular application.

30. In response to Appellant's arguments with respect to Issue 2, specifically claims 3 and 16, Appellant contends that nothing in Lethi or Bowden et al teaches a plurality of markings for cutting a nasal catheter to a desired length. It should be noted that in claims 3 and 16, Appellant does not recite the intended use in the claim, i.e. "for cutting a nasal catheter to a desired length" and as such the Examiner maintains the rejection of claims 3 and 16 over Lethi in view of Bowden et al for the teaching of a plurality of markings.

31. In response to Appellant's arguments with respect to Issue 3, specifically claims 4 and 17, Appellant contends that nothing in Lethi or Brain teaches a desirability for combining the two references to provide for a radio-opaque stripe. Brain in Col. 6, lines 4-8 specifically teaches that a radio-opaque stripe allows for easy identification of the

location of a tube which is sufficient motivation for one of ordinary skill in the art to include such a stripe in the device of Lethi.

32. In response to Appellant's arguments with respect to Issue 5, specifically claims 7 and 19, Appellant contends that nothing in Lethi or Spofford et al teaches a desirability for combining the two references to provide for a hydrophilic coating. Spofford et al specifically teaches that a hydrophilic coating would limit adhesion and subsequent build-up of mucous-type materials which would restrict the flow of oxygen through the catheter, which is sufficient motivation for one of ordinary skill in the art to include such a coating in the device of Lethi since the Lethi device is inserted into the nasopharynx region, a region that houses mucous-type materials.

33. With respect to Issue 6, the Examiner is not clear as to what exactly/specifically are Appellant's arguments with respect to the rejection of claims 9, 10, 21, 22, 26, and 27. Regardless, the Examiner maintains the rejections set forth with respect to claims 9, 10, 21, 22, 26, and 27. In response to Appellant's statement that "Daniell et al discloses an apparatus for supplying humidified, heated gases via face mask for treatment of sleep apnea," if Appellant's implications with respect to that statement is that Daniell et al teach a face mask rather than a nasopharyngeal tube/catheter, then it should be noted that the Examiner relied on the Daniell et al reference for a teaching of heating or humidifying gas delivered to a patient; and furthermore, Daniell et al provide a motivation to heat/humidify and that is to prevent dehydration or the airways and nasal passages.

34. For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Mital B. Patel
Examiner
Art Unit 3743

mbp
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Conferees

Henry Bennett
Supervisory Patent Examiner

Denise Pothier
Primary Examiner

Henry Bennett
Supervisory Patent Examiner
Group 3700

THOMAS S. BIRNEY, ESQ.
DORR, CARSON, SLOAN & BIRNEY, P.C.
3010 E. 6TH AVENUE
DENVER, CO 80206